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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,813	02/27/2002	Carl Saxinger	215875	6159

23460 7590 11/13/2003

LEYDIG VOIT & MAYER, LTD
TWO PRUDENTIAL PLAZA, SUITE 4900
180 NORTH STETSON AVENUE
CHICAGO, IL 60601-6780

EXAMINER	
PARKIN, JEFFREY S	

ART UNIT	PAPER NUMBER
1648	7

DATE MAILED: 11/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	10/084,813	SAXINGER, CARL	
	Examin r	Art Unit	
	Jeffrey S. Parkin, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *01* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2002*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24,30,31,34-36,50 and 53-69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-24, 30, 31, 34-36, 50, 53-69* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Restriction Requirement

35 U.S.C. § 121

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

a. Group I, claim(s) 1-10, 30, 56, 57, drawn to a human **CCR5** chemokine receptor **polypeptide** comprising an **YDIXYYXXE** core motif, classified in class 530, subclass 300.

b. Group II, claim(s) 11-16, 58, drawn to a human **CXCR4** chemokine receptor **polypeptide** comprising an **XEXIXIYXXXNYXXX** core motif, classified in class 530, subclass 300.

c. Group III, claim(s) 17-20, 59, drawn to a human **STRL33** chemokine receptor **polypeptide** comprising the amino acid sequence **EHQAFLQFS**, classified in class 530, subclass 300.

d. Group IV, claim(s) 21, 60, drawn to disparate human **CCR5 polypeptides lacking a common structural motif**, classified in class 530, subclass 300.

e. Group V, claim(s) 22, 61, drawn to disparate human **CXCR4** chemokine receptor **polypeptides lacking a common structural motif**, classified in class 530, subclass 300.

f. Group VI, claim(s) 23, 62, drawn to disparate human **STRL33** chemokine receptor **polypeptides lacking a common structural motif**, classified in class 530, subclass 300.

g. Group VII, claim(s) 24, 63, drawn to disparate human **CD4** cell surface antigen **polypeptides** lacking a common structural motif, classified in class 530, subclass 300.

h. Group VIII, claim(s) 31, drawn to a **nucleic acid** encoding a human **CCR5** chemokine receptor **polypeptide** comprising an **YDIXYYXXE** core motif, classified in class 536, subclass 23.5.

i. Group IX, claim(s) 34, drawn to a **method** of **making** an **antibody** through the **administration** of an immunogenic composition comprising a human **CCR5** chemokine receptor **polypeptide** comprising an **YDIXYYXXE** core motif, classified in class 424, subclass 185.1.

j. Group X, claim(s) 34, drawn to a **method** of **making** an **antibody** through the **administration** of a **nucleic acid vaccine** encoding a human **CCR5** chemokine receptor **polypeptide** comprising an **YDIXYYXXE** core motif, classified in class 424, subclass 185.1.

k. Group XI, claim(s) 35, drawn to a **method** of **inhibiting HIV infection** in a mammal through the **administration** of a human **CCR5** chemokine receptor **polypeptide** comprising an **YDIXYYXXE** core motif, classified in class 435, subclass 5.

l. Group XII, claim(s) 35, drawn to a **method** of **inhibiting HIV infection** in a mammal through the **administration** of a **nucleic acid** encoding a human **CCR5** chemokine receptor **polypeptide** comprising an YDIXYYXXE core motif, classified in class 435, subclass 6.

m. Group XIII, claim(s) 35, drawn to a **method** of **inhibiting HIV infection** in a mammal through the **administration** of an **anti-Id** human **CCR5** chemokine receptor polypeptide **antibody**, classified in class 435, subclass 7.1.

n. Group XIV, claim(s) 36, 50, drawn to a **method** of **making** an **HIV-1 gp120-specific antibody**, classified in class 424, subclass 208.1.

o. Group XV, claim(s) 53, drawn to an **immunogenic HIV-1 gp120 polypeptide**, classified in class 424, subclass 208.1.

p. Group XVI, claim(s) 54, drawn to an **HIV-1 gp120-specific antibody**, classified in class 424, subclass 148.1.

q. Group XVII, claim(s) 55, drawn to a **method** of **removing HIV from bodily fluids** using a human **CCR5** chemokine receptor **polypeptide** comprising an **YDIXYYXXE** core motif attached to a **solid matrix**, classified in class 424, subclass 140.1.

r. Group XVIII, claim(s) 55, drawn to a **method** of **removing HIV from bodily fluids** using an **anti-Id** human CCR5 chemokine receptor **antibody** attached to a **solid matrix**, classified in class 424, subclass 140.1.

s. Group XIX, claim(s) 64, drawn to a **nucleic acid** encoding a human **CXCR4** chemokine receptor **polypeptide** comprising an **XEXIXIYXXXNYXXX** core motif, classified in class 536, subclass 23.1.

t. Group XX, claim(s) 65, drawn to a **nucleic acid** encoding a human **STRL33** chemokine receptor comprising the amino acid sequence **EHQAFLQFS**, classified in class 536, subclass 23.1.

u. Group XXI, claim(s) 66, drawn to **nucleic acids** encoding disparate human **CCR5** polypeptides **lacking a common structural motif**, classified in class 536, subclass 23.1.

v. Group XXII, claim(s) 67, drawn to **nucleic acids** encoding disparate human **CXCR4** chemokine receptor **polypeptides lacking a common structural motif**, classified in class 536, subclass 23.1.

w. Group XXIII, claim(s) 68, drawn to **nucleic acids** encoding disparate human **STRL33** chemokine receptor **polypeptides lacking a common structural motif**, classified in class 536, subclass 23.1.

x. Group XXIV, claim(s) 69, drawn to **nucleic acids** encoding disparate human **CD4** cell surface antigen **polypeptides lacking a common structural motif**, classified in class 536, subclass 23.1.

2. The inventions are distinct, each from the other because of the following reasons:

3. Inventions I-VIII, XV, XVI, and XIX-XXIV are all unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, each of the identified groups is directed toward structurally and functionally different products (e.g., polypeptides, nucleic acids, and antibodies). Separate searches will be required for each identified group. Therefore, each group is clearly directed toward a different inventive concept.

4. Inventions IX-XIV, XVII, and XVIII are all unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, each of the identified groups is directed toward a different methodology that accomplishes different scientific objectives and employs different reagents and assay steps. Because of the unrelated subject matter, separate searches will be required for each identified group. Accordingly, each group is clearly directed toward an independent and distinct invention.

5. Inventions I and IX/XI/XVII are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the CCR5 polypeptide of Group I can be employed in a number of materially different processes such as immunization regimens, affinity binding protocols, and diagnostic assays.

6. Inventions VIII and X/XII are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the nucleic acid of Group VIII can be employed in a number of materially different processes such as immunization protocols and diagnostic assays.

7. Inventions XV and XIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the gp120 polypeptide of Group XV can be employed in a number of materially different processes such as immunization regimens, diagnostic assays, and affinity binding protocols.

8. Inventions I and X/XII-XIV/XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable

of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, the methodologies of Groups X/XII-XIV/XVIII neither require nor utilize the polypeptide of Group I.

9. Inventions II-VII and IX-XIV/XVII/XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, the methodologies of Groups IX-XIV/XVII/XVIII neither require nor utilize the products of Groups II-VII.

10. Inventions VIII and IX/XI/XIII/XIV/XVII/XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, the methodologies of Groups IX/XI/XIII/XIV/XVII/XVIII neither require nor utilize the nucleic acid of Group VIII.

11. Inventions XV and IX-XIII/XVII/XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, the methodologies of Groups IX-XIII/XVII/XVIII neither require nor utilize the HIV-1 polypeptide of Groups XV.

12. Inventions XVI and IX-XIV/XVII/XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P.

§ 806.04 and § 808.01). In the instant case, the methodologies of Groups IX-XIV/XVII/XVIII neither require nor utilize the antibody of Group XVI.

13. Inventions XIX-XXIV and IX-XIV/XVII/XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, the methodologies of Groups IX-XIV/XVII/XVIII neither require nor utilize the nucleic acids of Groups XIX-XXIV.

14. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, recognized divergent subject matter, and require separate searches, restriction for examination purposes as indicated is proper.

15. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. § 1.143). Applicant is also advised that the claims should be amended to reflect the election, where necessary.

16. Applicants are reminded that a restriction between product and process claims has been set forth *supra*. When applicant elects claims directed to the product, and a product claim is subsequently found to be allowable, withdrawn process claims that depend from or otherwise include **all** the limitations of the allowable product claim will be rejoined in accordance with the provisions of § 821.04 of the M.P.E.P. Process claims that depend from or otherwise include **all** the limitations of the patentable product

will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 C.F.R. § 1.116 while amendments submitted after allowance are governed by 37 C.F.R. § 1.312.

17. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. § 1.104. Thus, to be allowable, the rejoined claims **must** meet all criteria for patentability as set forth under 35 U.S.C. §s 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. **Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined.** See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer*, and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so will result in a loss of the right to rejoinder.** Furthermore, note that the prohibition against double patenting rejections of 35 U.S.C. § 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See M.P.E.P. § 804.01.

Correspondence

18. The Art Unit location of your application in the Patent and Trademark Office has changed. To facilitate the correlation of

related papers and documents for this application, all future correspondence should be directed to **art unit 1648.**

19. Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward the following Group 1600 fax number: (703) 872-9306. Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (703) 308-2227. The examiner can normally be reached Monday through Thursday from 8:30 AM to 6:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, Laurie Scheiner or James Housel, can be reached at (703) 308-1122 or (703) 308-4027, respectively. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Respectfully,

Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

10 November, 2003